University of Hertfordshire UH

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DATA MANAGEMENT SYSTEM VALIDATION

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for the validation of data management systems

SOP Number: gSOP-42-01	**Effective Date**: 05 June 2018
Version Number: 1.0	**Review Date:** 3 years (or as required)

1. BACKGROUND

This is a University of Hertfordshire standard operating procedure.

2. PURPOSE

This standard operating procedure applies to software used for UH sponsored/co-sponsored clinical trials that requires validation and verification to evidence that it is fit for its intended purpose.

3. APPLICABLE TO

Data managers, statisticians and anyone wishing to provide assurance that a system is operating to its specification and requirements and that it is fit for its intended purpose.

4. RESPONSIBILITIES

The statistician and data management team are responsible for the validation of the systems used for clinical trial data.

The CI has overall responsibility for ensuring the database meets all requirements.

5. PROCEDURE

There are three key features of computer system validation:

1) It demonstrates that the system was developed and implemented and is operated and maintained in a controlled manner throughout its life-time up to and including decommissioning
2) Results in a high degree of assurance that the system performs reliably and consistently and is therefore suitable for its intended purpose
3) Documentation is available to support the application of the controls.

Computer systems

All computer systems, both hardware and software, used for the collection and analysis of clinical trial data for CTIMPs must have undergone full validation checks. The results of which should be filed as evidence in the Trial Master File.

Whether the system to be used is a bespoke or commercial off-the-shelf (COTS) product in clinical trial activities the following should occur to demonstrate that it is fit for purpose:

- Validation of the development or installation of the computer system.
- Validation of any trial specific builds, applications, programming undertaken using the validated system.

Computerised laboratory information systems which capture test results conducted during a clinical trial are also part of the data management for CTIMPs and medical device trials. The CI/PI should ensure the accreditation status of the laboratory computerised system is suitable and that evidence of this is filed in the TMF.

Functional Specification

For bespoke system development a Functional Specification (FS) should be produced in addition to a User Requirements Specification. The Functional Specification provides details about the operations and activities that the system must be able to perform. It covers many aspects of the system that need to be documented. It should be used to verify that the implementation of the system performs according to the specification.

6. RELATED DOCUMENTS

- gSOP-40 Data Management Overview

7. APPENDICES

- Appendix 1 – Definitions

8. VERSION HISTORY/REVISIONS

Version Number	Effective Date	Reason for Change

9. AUTHORSHIP & APPROVAL

Author

Signature **Date**

Pro-Vice Chancellor (Research & Enterprise) Approval

Signature **Date**

10. AGREEMENT (MOVE ON TO SEPARATE SHEET BEFORE PRINTING)

Please detach and retain within <u>your training files</u>

I have read and understood the contents and requirements of this SOP (ref gSOP-042-01) and accept to follow University policies implementing it.

Recipient
Signature: ……Date: ……..
Name & Position: ……

Please retain copy of the signed form for your reference in your training file

Appendix 1 – Definitions

Validation
The assurance that a system meets the needs of the customer and other identified stakeholders

Verification
The evaluation of whether a system complies with the requirements and specification of the system

Software Requirements
The business needs for the system are defined in terms of the user, system and interface needs of the system.

Functional Specification
A functional specification documents the operations and activities that a system must be able to perform.

Installation Qualification
Installation Qualification verifies the proper installation and configuration of a system

Operational Qualification
Operational Qualification verifies the proper functioning of a system

Performance Qualification
Performance Qualification validates that a system performs according to the user requirements of the system and is therefore fit for purpose